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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,311	10/23/2003	Raymond E. Counsell	66254-5003-US01	8570

43850 7590 08/27/2007  
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EXAMINER
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JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/692,311	Applicant(s) COUNSELL ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 48,49 and 51-146 is/are pending in the application.
- 4a) Of the above claim(s) 48,49 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-82 and 84-146 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/07</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 6/8/07 wherein the specification was amended and claims 1-47, 50, were canceled and claims 51-146 were added.

**Note:** Claims 48, 49 and 51-146 are pending.

## **WITHDRAWN CLAIMS**

2. Claims 48, 49, and 83 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

3. The Applicant's arguments and/or amendment filed 6/8/07 to the rejection of claims 1-5, 7, 8, 14-30, and 50 made by the Examiner under 35 USC 102, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

**Note:** It is noted that while Applicant has canceled the majority of claims over which the 102, 112, and double patenting rejections were made, some of the newly added claims are rejectable under the same rejections.

### **Double Patenting Rejection**

Applicant asserts that the double patenting rejection is moot because of the claim amendment (e.g., claims 1-4) have been canceled.

The newly added claims read on US Patent No. 6,645,643. Thus, the rejection is MAINTAINED as set forth below.

Claims 51-53, 55-68, 70-89, 91-104, and 106-123 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,645,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to emulsions comprising a derivatized polyethylene glycol, a sterol, emulsifier, osmolality adjusting agent (glycerol), anti-oxidant (alpha tocopherol), and a lipid, and optionally a radioimaging agent (see patented claim 6). The claims differ in that the patented claims do not specify whether the particles of the oil-in-water emulsion are surrounded by amphiphilic or polar lipids. However, it would be obvious to one of ordinary skill in the art that the lipid of the patented invention reads on both amphiphilic and polar lipids because the patented claims broadly read on 'lipids'.

**112 First Paragraph Rejection (Prevention/Inhibition Claims)**

Applicant asserts that the claims have been amended to overcome the rejection. In particular, the claims have been amended to replace 'prevent' with 'inhibit'.

Applicant's arguments are found non-persuasive for the reason set forth below. The Examiner reviewed Applicant's specification for the term 'inhibit' and a definition thereof. However, a definition of such term was not found in the disclosure. Thus, the term 'inhibit' was given its broadest interpretation as set forth in the standard Webster's Dictionary. The term 'inhibit' encompasses 'prevention' since a definition was not set forth by Applicant in the disclosure. According to Webster's Dictionary, (New Riverside University Dictionary, 1984, page 629), the term 'inhibit' is defined as 'to restrict or hold

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back'; 'restrain'; 'to prohibit'; or 'forbid'. Furthermore, according to Webster's Dictionary, the term 'forbid' means 'to command one not to do something or prohibit'. The term 'prohibit' means 'to forbid by authority or to prevent'. Thus, replacing the term 'prevent' with 'inhibit' in the claims does not exclude the claims from the concept that the method (and/or compound/composition) reads on prevention.

Hence, claims 76, 77, 113, and 114 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for the preventing (inhibiting) of oxidation of the emulsion. The rejection is MAINTAINED for reasons of record in the office action mailed 12/8/06.

### **112 Second Paragraph Rejections**

The 112 rejections are WITHDRAWN because Applicant has canceled all the appropriate claims.

### **102 Rejection**

The 102 rejection is WITHDRAWN for reasons of record in Applicant's response filed 6/8/07.

## **NEW GROUNDS OF REJECTIONS**

### **103 Rejection**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 51-82 and 84-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modi (US Patent No. 6,214,375) in view of Wheeler et al (Journal of Pharmaceutical Sciences, 1994, Vol. 83, No. 11, pp. 1584-1564).

**Modi** discloses phospholipids compositions that comprise a medicinally active agent, at least three phospholipids, and at least two biodegradable polymers. The compositions may be used for various uses (see entire document, especially, abstract). The compositions may be in lamellar, vesicle, or other form, depending on the particular components of the compositions (column 4, lines 11-13). In addition, the composition may comprise an antioxidant such as tocopherol (column 4, lines 30-35). The method of making the composition involves dissolving the components of the composition in an organic solvent such as ethanol or chloroform/methanol (note that the solvents are non-ionic) [column 5, lines 23-34]. In column 8, claim 1, one may select the following components which overlap with the claims of the instant invention: dioleoyl phosphatidylcholine (emulsifier), triolein (non-polar lipid); cholesterol (sterol); glycerol (osmolality adjusting agent); and polyethylene glycols having molecular weights of 1,000 to 100,000, methoxypolyethylene glycol, or ethoxypolyethylene glycol. However, Modi fail to disclose the use of a contrast agent (agent containing radioactive marker).

**Wheeler et al** disclose polyethylene glycol modified phospholipids stabilized emulsions prepared from triacylglycerol. In particular, Wheeler et al disclose emulsion particles prepared in the presence of distearoylphosphatidylcholine (DSPC); cholesterol. [3H]-MePEGS-2000 distearoylphosphatidylethanolamine (DSPE) and [14C]triolein was used as radioactive markers for the emulsion (see entire document, especially, page

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1559, first column, 'Preparation of Emulsion', second column, second and third complete paragraphs).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching of Modi and incorporate a radiopharmaceutical into the emulsion because of the expectation of beneficial properties such as because the emulsion contains a radioactive marker, one would be able to administer the emulsion to a subject and monitor the substance in the subject. In particular, the presence of a marker would allow one to conduct diagnostic and therapeutic test on the subject. Furthermore, it should be noted that it would be obvious to combine the reference teaching because both Modi and Wheeler et al disclose triolein. However, in Wheeler et al the triolein contains the radioactive marker.

#### **COMMENTS/NOTES**


6. It should be noted that the claims read on Applicant's elected species for Group I wherein the non-polar lipid is triolein; the polar lipid emulsifier is dioleoylphosphatidylcholine; and the sterol is cholesterol. It should be noted that the product of elected Group I does not require an osmolality adjusting agent, and antioxidant, or a radiopharmaceutical.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones  
Primary Examiner  
Art Unit 1618

August 17, 2007